1. Name of the medicinal product

CEFIXIME TABLETS USP 400 MG

2. Qualitative and quantitative composition

SR. NO.	NAME OF THE INGREDIENTS	PHARMACOPEIAL SPECIFICATION	LABEL CLAIM	OVERAGES %	QTY. / TABLET	PURPOSE
ACTIVE INGREDIENTS						
1.	Cefixime (As Trihydrate) Eq. to Anhydrous Cefixime*	USP	(447.669 mg) 400.00 mg	2.75 %	460.000 mg	API
INACTIVE INGREDIENTS						
2.	Maize Starch	BP	-	0.00 %	233.000 mg	Diluent
3.	Dibasic Calcium Phosphate	BP	-	0.00 %	200.000 mg	Diluent
4.	Povidone	BP	-	0.00 %	20.000 mg	Binder
5.	Isopropyl Alcohol**	BP	-	0.00 %	0.250 ml	Solvent
6.	Colloidal Silicon Dioxide	USP	-	0.00 %	5.000 mg	Glidant
7.	Sodium Lauryl Sulphate	BP	-	0.00 %	10.000 mg	Surfactant
8.	Purified Talc	BP	-	0.00 %	14.000 mg	Glidant
9.	Magnesium Stearate	BP	-	0.00 %	8.000 mg	Lubricant

3. Pharmaceutical form

Oral Tablet

4. Clinical particulars

4.1 Therapeutic indications

- Cefixime Tablets USP 400 mg tablet is indicated for the treatment of infections caused by susceptible bacteria.
- Upper respiratory tract infections e.g. Otitis media and other URTI such as pharyngitis and tonsillitis.
- Lower respiratory tract infections e.g. Acute Bronchitis and Acute Exacerbations of Chronic Bronchitis.
- Uncomplicated urinary tract infections e.g. cystitis, cystourethritis, pyelonephritis.

4.2 Posology and method of administration

Adults: The recommended dose of Cefixime is 400 mg daily.
Children between 5-10 years: 200 mg daily

Method of administration: For oral use.

4.3 Contraindications

Cefixime Tablets contraindicated in patients with known allergy to the cephalosporin group of antibiotics.

4.4 Special warnings and precautions for use

- Cefixime Tablets should be advocated with caution in presence of renal impairment or GI disease, particularly colitis. Prolonged use of Cefixime Tablets could result in overgrowth of non-susceptible organisms. If superinfections occur (usually involving Aerobacter, Pseudomonas or Candida spp)
- Cefixime Tablets should be discontinued and/or appropriate therapy instituted.
- Periodic assessment of hematopoietic function is advisable during prolonged Cefixime Tablets therapy.
- Cefixime Tablets is not ideally meant for pregnant lady or lactating mother
- however, it could be only if strictly necessary.
- Nursing discontinuation temporarily must be considered whilst taking Cefixime Tablets.
- Safety and efficacy of Cefixime Tablets in children less than 6 months old have not been established.
- Cefixime Tablets must be coadministered with carbamazepine, warfarin and other anticoagulants.

4.5 Interaction with other medicinal products and other forms of interaction

Carbamazepine: Elevated carbamazepine levels have been reported in postmarketing experience when Cefixime is administered concomitantly. Drug monitoring may be of assistance in detecting alterations in carbamazepine plasma concentrations.
Warfarin and Anticoagulants: Increased prothrombin time, with or without clinical bleeding, has been reported when Cefixime is administered concomitantly.

4.6 Fertility, pregnancy and lactation

The use of AIIRAs is not recommended during the first trimester of pregnancy. The use of Al IRAs is contra-indicated during the second and third trimester of pregnancy.
Epidemiological evidence regarding the risk of teratogenicity following exposure to ACE inhibitors during the first trimester of pregnancy has not been conclusive; however a small increase in risk cannot be excluded. When pregnancy is diagnosed, treatment with Al IRAs should be stopped immediately and, if appropriate, alternative therapy should be started.
AIIRAs therapy exposure during the second and third trimesters is known to induce human fetotoxicity (decreased renal function, oligohydramnios, skull ossification retardation) and neonatal toxicity (renal failure, hypotension and hyperkalaemia).

Infants whose mothers have taken AIIRAs should be closely observed for hypotension.
Because no information is available regarding the use of Cefixime Tablets during breastfeeding, Cefixime Tablets are not recommended and alternative treatments with better established safety profiles during breast-feeding are preferable, especially while nursing a newborn or preterm infant.

4.7 Effects on ability to drive and use machines

In the case of side effects such as encephalopathy (which may include convulsion, confusion, impairment of consciousness, movement disorders), the patient should not operate machines or drive a vehicle.

4.8 Undesirable effects

- Diarrhea that is watery or bloody;
- Fever, sore throat, and joint pain with a severe blistering, peeling, and red skin rash;
- Numbness or tingly feeling;
- Warmth, redness, or tingling under your skin;
- Swelling in your hands or feet;
- Fast or pounding heartbeats;
- Chest pain, shortness of breath
- Mild nausea, stomach pain, constipation, loss of appetite;
- Anxiety, drowsiness;
- Increased night-time urination;
- Headache;
- Runny nose, sore throat, cough; or
- Vaginal itching or discharge.

4.9 Overdose

Symptoms:
Experience in adults exposed to doses of up to 900 mg/day for 8 weeks revealed no toxicity. The most likely manifestations of overdose are expected to be hypotension and tachycardia; bradycardia might also occur from overdose.
Treatment:
No specific information is available on the treatment of overdose with Cefixime. The patient should be closely monitored, and the treatment should be symptomatic and supportive. Suggested measures include induction of emesis and/or gastric lavage. Activated charcoal may be useful in the treatment of overdose. Cefixime is not removed by haemodialysis.

5. Pharmacological properties
5.1 Pharmacodynamics properties

Pharmacotherapeutic group: third generation cephalosporin, **ATC code:** J01DD08
Mechanism of action: Antimicrobial Spectrum: Cefixime is a semi-synthetic third generation oral cephalosporin with a broad spectrum of antibacterial activity against many Gram positive and Gram negative bacteria. It is highly stable in presence of beta-lactamases. Cefixime Tablets is bactericidal to a wide range of organisms including:

Gram Positive: Streptococcus pneumoniae, Streptococcus pyogenes, Streptococcus agalactiae.
Gram Negative: Hemophilus influenzae, Moraxella catarrhalis (Branhamella catarrhalis), Escherichia coli, Proteus vulgaris, Klebsiella species, Pasteurella multocida, Providencia species, Salmonella species, Shigella species, Citrobacter spacies, Neisseria gonorrheae.
Cefixime is not effective against Pseudomonas spp, group D streptococci (including enterococci), Listeria monolcytogenes, most staphylococcal strains (including methicillin-resistant strains), Enterobacter spp, and most strains of bacteroides and clostridia.

5.2 Pharmacokinetic properties

Absorption: Absorption of Cefixim is 40-50% with or without food. The time to maximal absorption is 0.8 hours when Cefixime Tablets is given with food.
Plasma Levels: Peak plasma concentrations (Cmax) are produced 2 to 5 hours (Tmax) with a single dose of Cefixime Tablets With doses of 200 to 400 mg, average Cmax is 3 mcg/ml and 4.6 mcg/ml respectively. The Cmax and area under the curve (AUC) are 10-25% with oral suspension as compared to tablets after doses of 100-400 mg of Cefixime tablet. Average AUCs are 40% higher at steady state. The plasma half-life of Cefixime Tablets is 3-4 hours, and may range up to 9 hours. The serum protein binding is concentration-independent and the bound portion constitutes 65%. It achieves extremely high concentrations in bile following Cefixime Tablets administration.
Elimination: Approximately 50% of Cefixime tablet's dose is excreted in urine in 24 hours; over 10% of intake is also eliminated via bile.

5.3 Preclinical safety data

No data found

6. Pharmaceutical particulars

6.1 List of excipients

- Maize Starch
- Dibasic Calcium Phosphate
- Povidone
- Isopropyl Alcohol
- Colloidal Silicon Dioxide
- Sodium Lauryl Sulphate
- Purified Talc
- Magnesium Stearate

6.2 Incompatibilities

None

6.3 Shelf life

31 months

6.4 Special precautions for storage

Store in a dry place below temperature 30^0C.

6.5 Nature and contents of container

10 X 1 X 10 Tablets Alu-Alu pack, packed in printed and laminated carton.

6.6 Special precautions for disposal and other handling

Not Applicable

7. Marketing authorization holder

West Coast Pharmaceutical Works LTD, Ahmedabad

8. Marketing authorization number(s)

Not Applicable

9. Date of first authorization/renewal of the authorization

Not Applicable

10. Date of revision of the text

November , 2023